K070309
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SEP 12 2008 **510(K) SUMMARY**

Pursuant to Section 12 Part (a) (i) 3A of the Safe Medical Devices Act of 1990 Quinnova Pharmaceuticals Inc. is providing a summary of the safety and effectiveness information available for Neosalus as well as the substantial equivalence decision making process used for Neosalus.

**Sponsor/Applicant Name and Address:**
Quinnova Pharmaceuticals, Inc.
411 South State Street
3rd Floor
Newtown, PA 18940

**Sponsor Contact Information:**
Jeffrey Day, President and CEO
Phone: 215-860-8263
Fax: 215-860-8265
e-mail: JDay@quinnova.com

**Date of Preparation of 510(k) Summary:**
September 05, 2008

**New Device Trade/Proprietary Name:**
Neosalus

**Device Common/Classification Name:**
Dressing. Wound and Burn. Hydrogel with Drug and/or Biologic

**Predicate Devices Name and 510(k) Numbers:**
Mimyx Cream (K041342) and Biafine Wound Dressing Emulsion (K964240)

**Device Description:**
Neosalus is fragrance-free, water-soluble foam dressing formulated for the management and relief of irritation experienced with various types of dermatoses including atopic dermatitis and allergic contact dermatitis. Neosalus is intended for topical application.

**Intended Use:**
Neosalus is a non-sterile formulation intended for topical application. It is intended for prescription use for the management and relief of irritation associated with various types of dermatoses including atopic dermatitis and allergic contact dermatitis.

**Performance Data:** All predicate devices referenced are non-sterile formulations that are applied topically to relieve the symptoms of various dermatoses.

**Conclusions:**
Based on the 510(k) summaries (21CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the predicate devices under the Food Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2008

Quinnova PHarmaceuticals
% Mr. Jeffrey Day
CEO & President
411 S. State Street, 3rd Floor
Newtown, Pennsylvania 18940

Re: K070309
Trade/Device Name: Neosalus
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 5, 2008
Received: September 8, 2008

Dear Mr. Day:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# INDICATIONS FOR USE

**510(k) Number (if known):**

K070309

**Device Name:**

Neosalus

**Indications for Use:**

Neosalus is indicated for management and relief of irritation associated with various types of dermatoses, including atopic dermatitis and allergic contact dermatitis.

**Prescription Use __X__** (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use _____** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH-Office of Device Evaluation [ODE]

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070309